K110020

510(k) Summary

Teratech Corporation

Terason™ t3200 Ultrasound System

JAN 2 0 2011

1. **Sponsor:**

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Charles F. Hottinger, Ph.D, RAC,
Regulatory Affairs Consultant
Telephone: 206-780-7945

Date Prepared: November 1, 2010

2. **Device Name**

Proprietary Name: Terason™ t3200 Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. **Predicate Device**

Terason™ Echo/t3000 Ultrasound System (K080234)

4. **Intended Use**

The Teratech Corporation Terason™ t3200 is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Intra-operative (abdominal, thoracic and PV); Pediatrics, Small Organ (Breast, testes, thyroid); Neonatal and Adult

Cephalic; Trans-rectal and Trans-vaginal; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

5. Device Description

The Terason™ t3200 is a modified version of the Echo/t3000 Ultrasound System. The modifications include improved transducer acoustic arrays, an improvement in the ultrasound beam forming engine to improve the bandwidth of the receive signal processing capability and improvements in the software for workflow and ease of use of the system.

6. Technology Characteristics

The design and construction of the Terason™ t3200 is similar to the Terason™ Echo/t3000 Ultrasound system. These systems utilize a laptop computer running Windows to run the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. The engine is housed in a compartment that is attached to the bottom of the laptop.

The differences between the Terason™ t3200 and the Terason Echo/t3000 Ultrasound System (the predicate device) include the following:

- The engine has a slight modification in the custom beamformer chip (as compared to the Terason Echo/t3000 system) that provides for improved filtering of the return signal for wider bandwidth and better resolution across the whole image field.
- The ultrasound application software has been modified to improve the user workflow and ease of use. The screen layout has been modified, and the user controls have been changed for better efficiency for the targeted exam types.
- Transducers have been improved by utilizing new acoustic arrays.

  15L4: Same housing construction as the 12L5 and 7L3 used on the previously cleared Echo/t3000 ultrasound system. The acoustic array is new with improved sensitivity and wider bandwidth than the 12L5.

  6C1: Same material construction as used on the 15L4. The acoustic array is new with improved sensitivity and wider bandwidth

than the previously cleared 5C2 used on the Echo/t3000 ultrasound system.

16HL7: Same identical transducer as used on the previously cleared Echo/t3000 ultrasound system (labeled 12HL7 on the Echo / t3000).

B1. Non Clinical Tests

The Terason™ t3200 system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety.
  - Intertek Test Record Number 100116897BOX-003

- IEC 62366, Medical Devices: Application of usability engineering to medical devices.
  - Intertek Project: 100116897BOX-005

- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
  - Intertek Project: 100116897BOX-006

- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
  - IEC60601-1-2 Intertek Test Record Number, 100116897BOX-013
  - IEC60601-1-2 Intertek Test Record Number, 100116897BOX-010

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
  - Transducer Model 6C1: Intertek Report Number IEC60601-2-37 t3200 6C1: 100116897BOX-008

- Transducer Model 15L4: Intertek Report Number IEC60601-2-37 t3200 15L4: 100116897BOX-007
- Transducer Model 16HL7: Intertek Report Number IEC60601-2-37 t3200 16HL7: 100116897BOX-009

- NEMA UD 3 Acoustic Output Display
  Terason t3200 Ultrasound System User Guide (16-3033)

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
  - Biocompatibility reports for all transducers (Attachments M-O of original submission)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Teratech Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JAN 20 2011

Re: K110020
Trade/Device Name: TERASON™ t3200 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, ITX, and IYN
Dated: December 30, 2010
Received: January 3, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the TERASON™ t3200 Ultrasound System, as described in your premarket notification:

Transducer Model Number

6C1
16HL7
15L4

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

JAN 20 2011

510(k) Number (if known): K110020

Device Name: _Terason Ultrasound Systems_____

Indications for Use:

The subject-modified device is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal; Abdominal; Intra-operative (abdominal, thoracic and PV); Laparosopic; Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Trans-rectal and Trans-vaginal; Musculo-skeletal Conventional and Superficial; Cardiac (adult & pediatric); Peripheral Vascular.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K110020

System: ____TERASON™ t3200 Ultrasound System____

Transducer: (see comments)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[e]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	N	N	N		N	N	N
	Abdominal[o]:	N	N	N		N	N	N
	Intra-operative (Spec.)[a,e]	N	N	N		N	N	N
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[o]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[o]:							
	Adult Cephalic[o]:							
	Trans-rectal[i]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[o]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[o]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	N	N	N		N	N	N
	Other (Specify)							

[a] Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

N= new indication

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[i] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110020

System: ____TERASON™ t3200 Ultrasound System____

Transducer: 6C1

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]	N	N	N		N	N	N
	Abdominal[e]:	N	N	N		N	N	N
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[e]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[c]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[c]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:	N	N	N		N	N	N
	Other (Specify)							

[a] Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

N= new indication

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[n] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110020

System: TERASON™ t3200 Ultrasound System

Transducer: 16HL7

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[e]:							
	Intra-operative (Spec.)[a,e]	N	N	N		N	N	N
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[e]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[e]:							
	Adult Cephalic[e]:							
	Trans-rectal[i]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[e]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[d]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[e]:	N	N	N		N	N	N
	Other (Specify)							

[a] Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).

[b] B+M; B+PWD; B+CD; B+DPD; B+PD

[c] Harmonic Imaging (HI)

[d] Incl. ultrasound guidance for placement of needles, catheters

[e] Abdominal organs and peripheral vessel.

[f] Incl. ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Incl. ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[n] Incl. guidance of amniocentesis, infertility monitoring of follicle development.

[i] Incl. stress echo.

N= new indication

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Evaluation and Safety

510(k) K110020

System: TERASON™ t3200 Ultrasound System

Transducer: 15L4

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[n]							
	Abdominal[o]:	N	N	N		N	N	N
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[o]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[d]:							
	Adult Cephalic[o]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[d]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[o]:	N	N	N		N	N	N
	Other (Specify)							

[a] Includes Color Dopp. (CD), Directional Power Dopp. (DPD), and (non-directional) Power Dopp. (PD).
[b] B+M; B+PWD; B+CD; B+DPD; B+PD
[c] Harmonic Imaging (HI)
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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